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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/308,397	05/18/99	GENTRY D	P50593

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EXAMINER	
FORMAN, B	
ART UNIT	**PAPER NUMBER**
1655	16

DATE MAILED: 04/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/308,397	GENTRY ET AL.	
	Examiner	Art Unit	
	BJ Forman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-33,37-42 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *25-33 37-42 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 April 2001 has been entered.

2. This action is in response to papers filed 29 January 2001 in Paper No. 12 in which claims 25, 30, 33, 37, 39, 42, 44 & 47 were amended and claims 34-35 & 43 were canceled. All of the amendments have been thoroughly reviewed and entered. All of the arguments have been thoroughly reviewed and are discussed below. The previous rejections under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph: Written Description of Office Action in Paper No. 9 dated 29 June 2000 are maintained.

Currently claims 25-33, 37-42 & 44-47 are under prosecution.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 25-33, 37-42 & 44-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claims are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of the first polynucleotide sequence

wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO: 1 (Claims 25-32 & 34-38), methods for producing the polynucleotide (Claim 33) an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 2 (Claims 39-41 & 44-46) and methods for producing the polypeptide (Claims 42 & 47). However, the specification fails to teach a specific utility for the claimed polynucleotide because the function of the polynucleotide or the encoded peptide is not known. The specification teaches the claimed polynucleotide sequences were identified in a DNA library derived from *Streptococcus pneumoniae* 0100993 (page 10, lines 19-20). However, the specification teaches that the polynucleotides may be obtained from other organisms (page 11, lines 27-30) and therefore, the polynucleotides are not *Streptococcus pneumoniae*-specific. The specification suggests that the peptides encoded by the claimed sequences have functions similar to the proteins of the malonyl-CoA:ACP family because polynucleotides encode a peptide having structural similarities to proteins of the malonyl-CoA:ACP family (page 10, lines 27-29). However, the specification does not teach a function for the peptides encoded by the claimed sequences wherein the teaching of a function would include a demonstration of the function (e.g. assays or experimental results). Neither the specification nor the prior art teach a specific utility for the claimed invention. Hence, the claimed polynucleotide and amino acid sequences lack a specific utility. Add therefore, the claimed methods are not supported by a substantial utility. The specification fails to assert any substantial utility for the polynucleotide and amino acid sequences and methods and neither the specification as filed nor any art of record discloses or suggests any utility such that a substantial utility would be established for the sequences and methods. The teaching of a substantial utility would include a real-world use e.g. a polynucleotide or amino acid sequence having a known function wherein expression inhibits or promotes a disease and wherein the method to detect the sequence is diagnostic for the disease. Additionally, the substantial teaching would include a demonstration of the real world use e.g. experimental results. The specification teaches that the claimed sequences may be used in diagnostic assays wherein detection of the sequences

will provide a diagnostic method for diagnosis of a disease (page 16, lines 12-14), for the presence of an infection (page 17, lines 20-22) and for the stage of infection and type of infection (page 14, lines 4-6). However, the sequences are not *Streptococcus pneumoniae*-specific (page 11, lines 27-30) and therefore, the specification does not teach a disease or infection for which the sequences may be diagnostic and the specification does not teach experimental results demonstrating the diagnosis. The specification teaches the sequences may be used to produce antibodies (page 17, lines 27-31) and the specification teaches the antibodies may be used to identify the polypeptides encoded by the sequences (page 18, lines 19-20). However, the specification does not teach a substantial utility for the anti-polypeptide antibodies (e.g. diagnostics) beyond the obvious detection of the polypeptide itself. The specification teaches the claimed sequences may have utility in the discovery of antibacterial compounds for treatment or inhibition of diseases (page 21, lines 9-10 and 26-27). However, the specification does not teach any antibacterial compounds discovered by using the claimed sequences. The specification teaches the claimed sequences may be used as an antigen for inducing an immunological response (page 22, lines 8-23) and for vaccine production (page 23, lines 22-27). However, the specification does not teach experimental results which demonstrate that the antigens produce an immunological response or have utility as vaccines. The specification does not teach any specific utility nor does the specification teach any substantial utility. Therefore the suggested uses for the claimed sequences are merely means to study the properties of itself. Hence, the specification fails to support a substantial utility for the claimed methods. Because the claimed methods are not supported by a specific or substantial utility that is either well known in the art or supported by the specification, the claimed methods are not supported by a well-established utility. The specification and the prior art fail to support a specific and substantial or well established utility for the claimed methods.

Response to Arguments

5. Applicant argues that the claimed polynucleotides and polypeptides have utility as diagnostic reagents for use in the detection of *Streptococcus pneumonia.* Applicants further argue that the claimed polynucleotides could be used to identify bacterial contamination wherein the bacteriological tests are indicative and not dispositive. These argument are not found persuasive because the recited uses are of a general utility and not specific and substantial or well established and because the specification teaches the claimed polynucleotides may be obtained from other organisms (page 11, lines 27-30). Therefore the claimed polynucleotides do not have a specific and substantial asserted utility or well established utility for the detection of *Streptococcus pneumonia.*

Response to Request for reconsideration

6. Applicant's arguments have been reconsidered, but again are not found persuasive for the reasons stated above.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 25-33, 37-42 & 44-47 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

First paragraph of 35 U.S.C. 112: Written Description

9. Claims 25-33, 37-42 & 44-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25-34 & 37-38 are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of the first polynucleotide sequence wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO: 1 and a process for producing the polypeptide encoded by SEQ ID NO: 1. Claims 39-47 are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of the first polynucleotide sequence wherein the first polynucleotide sequence encodes a polypeptide comprising of SEQ ID NO: 2 and a process for producing the polypeptide. The specification teaches the polynucleotide sequences of SEQ ID NO: 1, 3 and 5 and the amino acid sequences of SEQ ID NO: 2, 4 and 6. However, the claimed polynucleotide sequences are broadly defined in the specification (page 28, line 12-page 29, line3) and encompass a large genus of sequences, including genes, gene fragments, DNAs, cDNAs, RNAs, mRNAs, probes and primers each encompassing a large genus of possible sequence having various components, various lengths, various regions and degrees of complementation and various codon usage for amino acid encoding. The claims are broadly drawn to a polynucleotide sequence which is at least 95% identical to SEQ ID NO: 1. The clamed sequences 95% identical to SEQ ID NO: 1 encompasses a very large genus of sequences but the specification does not teach which nucleotide sequences are encompassed or excluded by the 95% or how to determine which sequences are encompassed e.g. an algorithm which determines identity. The specification does not teach a representative number of species of the genus encompassed by the claims. The specification teaches that the invention relates to isolated polynucleotides, including the full length gene, that encodes the FabD polypeptide (page 9, lines 29-30) and the specification teaches that polynucleotides broadly encompass any modified or unmodified single, double and triple stranded DNA and/or RNA (page 28, line 12-page 29, line 2). However, the specification does not teach a gene, the teaching of which would minimally include the open reading frame, introns, exons, and regulatory regions. The

specification does not teach a representative number of the claimed probes and primers, a teaching of which would minimally include the regions of SEQ ID NO: 1 to which they bind. The specification teaches SEQ ID NO: 1, 2, 3, 4, 5 & 6 but the specification does not teach a representative number of the claimed sequences in sufficient detail that one skilled in the art would reasonably conclude that inventor had possession of the claimed invention at the time the application was filed. The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude the inventor had possession of the claimed invention see *In re Vas-Cath*, Inc. 935F2d. 1555, 1563, 19 USPQ2d 1111,1116.

Response to Arguments

10. Applicant argues that because the claimed nucleic acids would typically be replicated in vectors comprising the necessary regulatory elements which are not described in the specification and therefore the subject matter not taught in the specification falls within what is conventional and well-known in the art. This argument is not found persuasive because the claims are written so broadly as to encompass a very large genus of sequences. The recitation "an isolated polynucleotide comprising a first polynucleotide sequence .....wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO: 1" encompasses a large genus of polynucleotides including genes and the specification does not teach the claimed genes or a representative number of the claimed species.

Applicant further argues Examples 8 and 11 set forth in the Written Description Guidelines teach examples of allowable claims having equivalent scope to the instant claims. This argument is not found persuasive because Examples 8 and 11 and the instant claims are different in scope. Specifically, in Example 8 the claim is drawn to an isolated nucleic acid sequence, SEQ ID NO: 2 and the specification teaches that SEQ ID NO: 2 consists of the complete ORF. The scope of Example 8 is limited to nucleic acid sequences comprising SEQ ID NO: 2 which is taught in the specification while the scope of the instant claims comprises a large genus of sequences not taught in the specification. Claim 1 of Example 11 is drawn to an isolated cDNA that encodes protein X (SEQ ID NO: 2) and the specification teaches one species of the claimed cDNA however, the Guidelines teach that one of skill could apply the genetic code to envision the claimed genus. The Guidelines teach that an adequate written description of Claim 1 is provided in the specification but Claims 2 and 3 being drawn to allelic variants of SEQ ID NO: 2 lack an adequate description. The scope of Example 11, Claim 1 is limited to a

cDNA that encodes SEQ ID NO: 2 which is taught in the specification while the scope of the instant claims being drawn to a large genus of sequences is much broader than either Example 8 or 11.

Response to Request for reconsideration

11. Applicant's arguments have been reconsidered, but again are not found persuasive for the reasons stated above.

First paragraph of 35 U.S.C. 112: New Matter

12. Claims 25-33, 37-42 & 44-47 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments to the claims recite "wherein the first polynucleotide sequence is not genomic DNA". The amendments are not part of the specification as originally filed and therefore are considered new matter. The originally filed specification recites the claimed molecules include mRNAs, cDNAs, genomic DNAs (page 3, lines 26-28) and therefore the new limitation "not genomic DNA" is considered new matter (see MPEP, 2163.01 and 37 C.F.R. 1.118). An amendment reciting "wherein the first polynucleotide sequence is mRNA or cDNA" would not be considered new matter.

Prior Art

13. Claims 39-47 are drawn to an isolated polynucleotide comprising a first polynucleotide sequence or the full complement of the entire length of the first polynucleotide sequence, wherein the first polynucleotide sequence encodes a polypeptide comprising SEQ ID NO: 2. Magnuson et al. (FEBS Letters, 1992, 299(3): 262-266) teach an isolated polynucleotide sequence encodes a polypeptide having 74.5% similarity to the sequence of SEQ ID NO: 2.

While the sequences of Magnuson et al. have similarity to the claimed sequences, they do not encode the claimed polypeptide.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this

application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
April 18, 2001